9- 41130

Food and Drug Administration
Atlanta District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

60 8th Street, N.E.
Atlanta, Georgia 30309

June 11, 2003

VIA FEDERAL EXPRESS

WARNING LETTER
(03-ATL-23)

Clark J. Hiebert
Owner
Rolling Acres Farm
4599 Hwy. 171 North
Louisville, Georgia 30434

Dear Mr. Hiebert:

An investigation of your cattle operation by Investigators Lawrence S. Newsom and Carlos A. Ortiz on May 20 – 28, 2003, confirmed that you offered an animal for sale for slaughter as food, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). The animal was adulterated food within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Act. In addition, your extra label usage, and the illegal tissue residues that resulted, caused the drug product Tilmicosin, to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about February 20, 2003, you sold a cow, identified with tag #57SH1666, to [redacted] in [redacted] This cow was sold for slaughter as human food. The United States Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS) analysis of tissue collected from that animal (Case No. 8-0307-03) disclosed the presence of high levels of the drug tilmicosin in the kidney and liver tissue. The liver was found to contain 10.94 parts per million (ppm) and the kidney contained 10.05 ppm of tilmicosin.

The tolerance established for residues of tilmicosin in the liver tissue of cattle is 1.2 ppm. No tolerance is established for tilmicosin residues in the kidney tissue of cattle. The tolerances for tilmicosin are listed in Title 21, Code of Federal Regulations, Part 556.735 (copy enclosed). The presence of this drug, at levels above the tolerance, in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that could allow medicated animals, bearing potentially harmful drug residues, to enter the food supply. For example, you lack an adequate system for assuring that animals which have been treated are withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. You have failed to assure that drugs are not used in a manner contrary to the directions contained in the labeling. Our investigators found that you had no animal

medication records that would identify which animal had been medicated, what type of medication had been used, the treatment date, the dosage administered, the route of administration, and what the withdrawal times should be. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

In addition, you are adulterating the veterinary drug Tilmicosin Injection, USP, within the meaning of Section 501(a)(5) of the Act, when you administer it to cattle in the manner you described to our investigators. You stated that you had found the drug on the farm and that it had not been prescribed by a veterinarian. You injected the cattle intramuscularly with an unknown amount of drug for an indication not approved for this product. The drug becomes adulterated when you fail to use it in accordance with its labeled instructions, or in compliance with extralabel use regulations. Use of the drug contrary to its labeled instructions, resulting in a residue which may present a risk to public health and which is above an established tolerance, causes the drug to be unsafe within the meaning of Section 512 of the Act.

The above-identified violations are not intended to be an all-inclusive list of deficiencies at your cattle farm. The investigators issued a list of Inspectional Observations (FDA 483) to you at the conclusion of their visit. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above and to establish procedures whereby such violations do not recur. Failure to do so may result in enforcement action being initiated by the FDA without further notice such as seizure and/or injunction.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that is sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,

Mary Woleske

Mary H. Woleske, Director
Atlanta District